Community-based Behavioural Activation Training (ComBAT) for Depression in Adolescents: Randomised Controlled Trial (RCT)

Participant Information Sheet: Parent/Guardian Version

We would like to invite your son/daughter/child to take part in the above trial. Before you decide if you are happy to support them with this, please read the following information.

What is the purpose of this study?

Depression is currently the leading cause of illness and disability in young people with approximately 20% of adolescents having had at least one depressive episode by the age of 18. Young people with low mood can experience lots of different symptoms, these can include sadness and irritability, loss of interest and pleasure, tiredness or lack of energy, loss of confidence, trouble with concentration and sleep, and changes in appetite. Low mood can affect many aspects of young people's lives including their relationships with others, education and physical health.

One therapy shown to be effective in treating low mood in adults is Behavioural Activation (BA) – a type of talking therapy focused on increasing activity. Although research supports its use with adults, less research has examined its use with young people. However, because BA focuses on some of the symptoms often experienced by young people with low mood, it could be a suitable alternative treatment for them. We have therefore developed a new version of BA for young people (aged 12 to 18 years) experiencing low mood. The treatment aims to help young people by encouraging them to engage in activities that they used to enjoy but may have stopped doing because they have felt down. The idea is that by taking part in activities that they used to enjoy, users of the BA may find that their mood improves.

The aim of this research is to examine the effectiveness of our BA and compare it to treatments usually offered to young people experiencing low mood.

Why have I been approached?

We are looking to recruit young people aged 12 to 18 years experiencing low mood to take part in the research. You have been approached as the parent/guardian of a young person who meets this criteria. Overall, we hope to recruit around 250 young people to participate.

What is BA?

Our treatment is based on Behavioural Activation (BA) which aims to improve people's mood by encouraging them to take part in activities that they may have stopped doing because they have felt down. Our BA is made up of 8 sessions each lasting around 30 to 40 minutes and delivered weekly. The sessions help young people to identify activities that are meaningful and enjoyable and are encouraged to take part in these with support provided. Young people will also be shown how to set goals, use problem solving, learn

methods to deal with stress and avoidance and will be taught what to do if they think they may have a relapse (i.e. are feeling better and then see symptoms return). All BA sessions have been developed from previous BA therapies and through discussions with professionals, parents/guardians and young people.

What treatment will my son/daughter/child receive if they choose to take part?

To see if our BA is helpful, we would like to compare this to other forms of support that are usually offered to young people experiencing low mood. Therefore if your son/daughter/child chooses to take part in the research they will either receive BA or the support that the service to which they belong to usually offers (e.g. another type of talking therapy, signposting elsewhere, etc).

Does my son/daughter/child have to take part?

Your son/daughter/child is under no obligation whatsoever to take part. It is entirely voluntary. Your son/daughter/child is free to withdraw from the study at any time, without giving a reason.

If your son/daughter/child would like to take part, we will ask both them and you to complete forms to confirm this. In the unlikely event that your son/daughter/child lost capacity to consent during their time in the study, we would withdraw them from the study but with their permission, use the information we have collected up until this point.

What will happen if my son/daughter/child takes part?

The person who gave you this form (e.g. a professional within a community or school-based service or somebody in an NHS service (e.g. CAMHS)) will have also given your son/daughter/child an expression of interest form and two questionnaires about their mood. These questionnaires are called the Revised Child Anxiety and Depression Scale (RCADS) depression subscale and the Patient Health Questionnaire-9 modified for adolescents (PHQ9-A). If your son/daughter/child would like to take part, we ask that they complete the expression of interest from and both questionnaires and return them to us. The questionnaires will give us a score which we will use to decide whether your son/daughter/child may be suitable to enter the study. If we think that their mood may be particularly low, we may arrange for them to talk to a clinical member of the research team about this. As the research is only designed to include young people with mild to moderate depression, taking part may not be suitable for your son/daughter/child if their symptoms are more, or less, severe. If this is the case, we will inform you and the person who has referred your son/daughter/child to the study of this. If your son/daughter/child is not eligible for the study, we will securely destroy any information you have provided to us. Whether they enter the study or not, your son/daughter/child will be able to access services as usual in the normal ways.

If your son/daughter/child is eligible to take part, a member of the research team will arrange to meet with you and them to talk about the research in more detail. This can be done face-to-face, over the telephone or using videoconferencing software depending on which you would prefer. At this meeting/conversation, your son/daughter/child will be

asked to complete a form to say they are happy to take part in the research. We will also ask for your permission for them to take part and ask you to complete a form too.

A member of the research team will then ask your son/daughter/child to fill in some questionnaires. These will include some questions about themselves (e.g. age, sex, ethnicity, etc) and some more about how they have been feeling recently. Filling in the questionnaires should take around 60 minutes although may be a little longer/shorter depending on the answers they give.

Following this meeting, your son/daughter/child will be randomly assigned (like when you flip a coin) by a computer to receive either BA or the usual support offered by the service who has recruited them to the research. A member of the research team will contact you to let you know which it is and arrange the timings of treatment sessions (as appropriate). With yours, and your son/daughter/child's permission, some treatment sessions might be audio-recorded, or a researcher may ask to come along and sit in on the session. This helps us to see how different support is being delivered.

What happens next?

Six months after your son/daughter/child's first meeting with the researcher, a member of the research team will contact you to arrange a second visit with them. Again, this can be face-to-face, over the telephone or via videoconferencing software depending on what you and your son/daughter/child would prefer. At this meeting, a researcher will ask your son/daughter/child to fill in the same questionnaires that they completed at the previous meeting (before they had received any support).

A member of the research team will also arrange to meet with your son/daughter/child 12 months after their first meeting. This third meeting will ask your son/daughter/child to complete the same questionnaires they have completed previously.

We will compare the questionnaires that your son/daughter/child completes at 6 and 12 months with those completed at the beginning of the research to see if the support they have received has helped.

We are interested in finding out what young people thought of the support that they received when taking part in the research. Therefore, we will also ask some young people if they are happy to have an extra, short interview with a researcher about what they thought about the support they have received. This will take place 6-months after they have joined the research.

What is my role if my son/daughter/child wants to take part?

If your son/daughter/child wants to take part, we would ask that you support them during their time in the research. This might involve helping them to get to treatment sessions (as appropriate) or discussing what they have done as part of the support they have received.

During their time in the research we would also ask you to monitor for any worsening in their symptoms and inform the person providing their support if you have any concerns.

If you feel that their symptoms of low mood have significantly declined and the professional supporting them is not available, please contact your son/daughter/child's GP. If you have serious concerns, we ask that you take them to their local A&E department or call 999. If the research team or the professional treating your son/daughter/child have any concerns, we will inform you.

What do I do if my son/daughter/child wants to take part?

If your son/daughter/child is happy to take part in the study, please complete the enclosed expression of interest form and return this, alongside their completed RCADS depression subscale and PHQ-9A questionnaires to us. These can be passed to us via the person who gave you this information or directly using the research team contact details on the bottom of the expression of interest form.

What are the possible risks?

We do not know of any risks of BA or of the usual care that your son/daughter/child may be offered, but you might find that they feel down when taking part in the research or notice that their symptoms have got worse (e.g. having trouble sleeping, change in appetite, irritability, change in ability to concentrate). Therefore, during the research it is very important that you and your son/daughter/child look out for signs of worsening mood. If this happens, we ask that you seek additional support if you feel it necessary. This may include contacting your son/daughter/child's supporting professional or GP. If you have any serious concerns, we ask that you take them to their local A&E department or call 999. If the research team or the professional who provides support to your son/daughter/child during the research (e.g. the person who provides therapy or signposts them to alternative support) felt that your son/daughter/child no longer had capacity to take part in the study at any point, they would be withdrawn. However, any data already collected would be kept.

Are there any advantages and disadvantages of taking part?

If your son/daughter/child chooses to take part in the study, they will receive the support they have been randomised to. This might include attending treatment sessions (as appropriate). They will also need to complete the questionnaires with the researcher and possibly attend an interview if happy to do so. We cannot be sure that BA or the usual care will work. However, we hope that the support that your son/daughter/child receives is useful in helping with their low mood and in learning some skills that they can use in the future if they feel down. By taking part your son/daughter/child will also be able to tell us what they think of the support they have received. This will be helpful in understanding more about the different support available for young people experiencing low mood and allowing us to improve support for young people in the future.

How will we use information about you?

- We will need to use information from yourself and your son/daughter/child for this research project.

- This information will include your names and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly.

- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

- We will keep all information about you safe and secure.

- Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

- All personal identifiable information will be destroyed at the end of the ComBAT 5-year programme of research and the rest of the information from the study will be destroyed after 10 years. We will keep this information for longer in case we need to check the results of the study.

What are your choices about how your information is used?

- Your son/daughter/child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

- We need to manage your son/daughter/child's records in specific ways for the research to be reliable. This means that we won't be able to let you or your son/daughter/child see or change the data we hold about them.

- If, during the research, a member of the research team or supporting professional identifies any safeguarding issues, confidentiality may be broken with the necessary professionals or supporting services notified of these issues.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to Dr Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk or the ComBAT research team, email: combat-project@york.ac.uk. or
- by ringing us on 07385430934.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [email: combat-project@york.ac.uk or call 07385430934). If you remain unhappy and wish to complain formally, you can do this by contacting the sponsors' Data Protection Officer at

TEAWVNT.AccessRequests@nhs.net or reporting your concerns to the Information Commissioner's Office at www.ico.org.uk/concerns.

In the event that something does go wrong, and you, or your son/daughter/child, are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against Tees Esk and Wear Valleys NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Who is conducting the research?

Researchers based in the Department of Health Sciences at the University of York are conducting this work in partnership with Tees, Esk and Wear Valleys NHS Foundation Trust who are the sponsor for the study. Professionals based in both organisations will be responsible for running the study.

Who is organising and funding the research?

This research is part of a 5-year research project that has been organised by The Department of Health Sciences at the University of York and the NHS. It has been paid for by a research grant from the National Institute for Health Research (NIHR).

Who has reviewed the study?

All research has to be checked by a research ethics committee before it can go ahead. This makes sure the research is safe and fair. This research has been reviewed and approved by North East - Newcastle and North Tyneside 1 Research Ethics Committee (reference: 22/NE/0100).

What will happen to the results of the study?

The results will be published in a study report and scientific journals. If your son/daughter/child tells us that they would like to know what we find in the research, we will send them a summary of the results when the study has finished.

Who can I contact if I want to learn more about the study?

If you would like further information about the study please contact Dr Lucy Tindall (lead researcher), email: lucy.tindall@york.ac.uk or the ComBAT research team, email: combat-project@york.ac.uk. If you have any queries or concerns about the research or would like to make a complaint please contact Professor Lina Gega (lina.gega@york.ac.uk) or PALS (Patient advice and liaison service), email: tewv.pals@nhs.net, Tel: 0800 052 0219.

Thank you for reading this. If you have any questions, please ask.